

**REMARKS**

Claims 1-22 were presented for examination and were rejected.

The applicants have amended claim 1 in order to incorporate the limitations recited in previous claims 2 and 4. Accordingly, the applicants have canceled claims 2 through 4 without prejudice, and reserve the right to re-add the canceled claims to this or another application.

The applicants have also amended claim 5 in order to update the claim dependency, as a result of the canceling of claim 3.

The applicants respectfully request reconsideration in light of the amendments and the following comments.

**Double Patenting Rejection of Claims 1-3, 4, and 5-9**

Claims 1-3 have been rejected under statutory double-patenting over U.S. Patent No. 6776194 B2.

The applicants have amended claim 1 in order to incorporate the limitations recited in claims 2 and 4.

Because claim 1 now recites what was previously recited in claim 4, and claim 4 was not part of the statutory double-patenting rejection, the applicants respectfully submit that the rejection is overcome.

Claim 4 has been rejected under obvious-type double-patenting as being unpatentable over U.S. Patent No. 6776194 B2 (hereinafter "US'194"). The limitations recited in claim 4 have been incorporated into claim 1, which now recites:

1. A method of determining the helix angle of a helical formation for a conduit, the method comprising specifying the internal dimensions of the conduit and an intended fluid mass flow through the conduit, and determining the helix angle from the pressure drop and the turbulent kinetic energy for a conduit having the specified internal dimensions and intended fluid mass flow, wherein the pressure drop and the turbulent kinetic energy are non-dimensionalised before the helix angle is determined, and *wherein the helix angle is determined as a helix angle at which the non-dimensionalised pressure drop and the non-dimensionalised turbulent kinetic energy are not equal.*

*(emphasis supplied)*

According to the Office, although the emphasized passage in claim 1 is not explicitly stated in the claims of US'194, the subject matter of this feature is "an obvious corollary to

one of ordinary skill in the art at the time of the invention." The applicants respectfully submit that there is no justification of the Office's assertion in US'194.

The Office has referred to claim 4 of US'194 which recites the feature "the helix angle is determined as the helix angle at which the non-dimensionalised pressure drop and the non-dimensionalised turbulent kinetic energy are substantially equal", (emphasis added). It is to be appreciated that this is completely the opposite from what is recited in amended claim 1 whereby the non-dimensionalised pressure drop and the non-dimensionalised turbulent kinetic energy are not equal. The applicants respectfully submit that the exact opposite of what is explicitly stated in US'194 cannot be categorically regarded as "an obvious corollary."

A brief discussion of US'194 is offered here, in order to draw a distinction between the prior art and the present invention as defined in amended claim 1. In column 6, lines 24 to 26, US'194 teaches that "that choice of helix angle is a compromise between minimizing pressure drop and minimizing turbulent kinetic energy." The patent then goes on to state that "that optimum helix angle for the graft occurs at approximately when the non-dimensionalised pressure drop is approximately equal to the non-dimensionalised turbulent kinetic energy", (see column 6, lines 44 to 48). Accordingly, the reasoning behind US'194 is clearly that the optimum helix angle will be at the helix angle where the two parameters are equal, as is depicted in Figure 11 of US'194. There is absolutely no reason why a skilled person would consider departing from this teaching, since US'194 is clear as to how to achieve an optimum result.

In contrast, the present invention as defined in amended claim 1 is based on the observation that, under some circumstances, minimizing the parameter of pressure drop is actually more significant than minimizing the turbulent kinetic energy in a conduit, and vice-versa. For example, in vascular disease, in certain situations a significant pressure drop is not thought to be advantageous (for example in longer conduits and ones where outflow pressure should be maximized such as in a peripheral arterial graft). In other situations, turbulent kinetic energy acts to stimulate tissue response and thus leads to conduit failure; therefore, it is important to reduce turbulent kinetic energy and accept a higher pressure drop (e.g., in dialysis access in a fistula conduit). Since US'194 provides no suggestion of any circumstances where it would not be optimum to comprise the turbulent kinetic energy and pressure drop equally, there is no reason why a skilled person would consider the present invention as defined in amended claim 1 to be obvious.

For these reasons, the applicants respectfully submit that the rejection of claim 4 (now part of claim 1) is traversed.

Claims 5-9 have been rejected under obvious-type double-patenting as being unpatentable over US'194" in view of Houston *et al*. Because claims 5-9 are dependent on claim 1, and because Houston *et al* fails to cure the deficiencies of US'194 with respect to the rejection of claim 1, the applicants respectfully submit that the rejection of claims 5-9 is also overcome.

**35 U.S.C. 102 Rejection of Claims 10, 11, and 14-22**

Claims 10, 11, and 14-22 were rejected under 35 U.S.C. 102(b) as being anticipated by Houston *et al*, WO 00/38591 (hereinafter "Houston *et al*"). The applicants respectfully traverse the rejection.

Claim 10 recites:

**10.** A helical formation for a conduit, the helical formation defining at least a portion of a helix, the angle of the helix defined by the helical formation being determined from the internal dimensions of the conduit, the fluid mass flow of the conduit, the pressure drop along the conduit and the turbulent kinetic energy within the conduit.

*(emphasis supplied)*

Nowhere does Houston *et al* teach or suggest, alone or in combination with the other references, what claim 10 recites — namely the helix angle being determined from the pressure drop along the conduit and the turbulent kinetic energy within the conduit.

While Houston *et al* does disclose a helical formation for a conduit, it states that "the optimal helix angle will be determined by factors such as the diameter, longitudinal velocity and rotational velocity" (see page 3, paragraph 3 of Houston *et al*). There is no reference in Houston *et al* to determining the helix angle from the "pressure drop along the conduit" and "the turbulent kinetic energy within the conduit." There is no explicit reference to the "fluid mass flow of the conduit" in Houston *et al*. As such, there appears to be absolutely no justification for the Office's line of rejection since features of claim 10 are neither explicitly stated in Houston *et al* nor are inherent from it, on account of it being clear that the helix angle can be determined in a different manner such as with reference to diameter, longitudinal velocity, and rotation of velocity.

For these reasons, the applicants respectfully submit that the rejection of claim 10 is traversed.

Because claims 11 and 14-18 depend on claim 10, the applicants respectfully submit that the rejection of them is also traversed.

Claim 19 recites:

**19.** A conduit comprising a helical formation, the helical formation defining at least a portion of a helix, the angle of the helix defined by the helical formation being determined from the internal dimensions of the conduit, the fluid mass flow of the conduit, the pressure drop along the conduit and the turbulent kinetic energy within the conduit.

*(emphasis supplied)*

As in the case of claim 10 discussed above, nowhere does Houston *et al* teach or suggest, alone or in combination with the other references, what claim 19 recites — namely the helix angle being determined from the pressure drop along the conduit and the turbulent kinetic energy within the conduit.

For the reasons discussed above and with respect to the rejection of claim 10, the applicants respectfully submit that the rejection of claim 19 is also traversed.

Because claims 20-22 depend on claim 19, the applicants respectfully submit that the rejection of them is also traversed.

### **35 U.S.C. 103 Rejection of Claims 12 and 13**

Claims 12 and 13 have been rejected under 35 U.S.C. 103 as being unpatentable over Houston *et al*.

Because claims 12 and 13 are dependent on claim 10, and because the applicants have traversed the rejection of claim 10 as discussed above, the applicants respectfully submit that the rejection of claims 12 and 13 is also traversed.

### **Request for Reconsideration Pursuant to 37 C.F.R. 1.111**

Having responded to each and every ground for objection and rejection in the last Office action, applicants respectfully request reconsideration of the instant application pursuant to 37 CFR 1.111 and request that the Examiner allow all of the pending claims and pass the application to issue.

If there are remaining issues, the applicants respectfully request that Examiner telephone the applicants' attorney so that those issues can be resolved as quickly as possible.

Respectfully,  
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